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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/819,813

Applicant(s)

KENDRUP ET AL

Examiner

Amy E Pulliam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt is acknowledged of the Declaration, Information Disclosure Statement, Priority Paper, Preliminary Amendment A, and Supplemental Information Disclosure Statement, received by the Office, May 22, 2001, March 29, 2001, May 22, 2001, March 29, 2001, and March 27, 2002, respectively.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase preferably renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. The scope of the claim is unclear. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 7, 8, 9, 11, 12, 13, 14, 15, 16, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,639,476 to Oshlack *et al.*.

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Applicant is claiming a method for producing a controlled release pharmaceutical preparation comprising preparing a drug containing core, suspending a pore forming agent in an aqueous dispersion of a film forming polymer, coating the solid core with the suspension, and drying the coated substrate.

Oshlack *et al.* disclose a controlled release dosage form, comprising a substrate containing an active agent, said substrate being coated with a plasticized aqueous dispersion consisting essentially of copolymers which are copolymers of acrylic acid and methacrylic acid esters, and a further material which can be a pore-former. Oshlack *et al.* further teach that the coating is applied to the substrate, and the coated substrate is cured at a temperature greater than the glass transition temperature of the aqueous dispersion of said plasticizer water-insoluble polymer. See column 36, claim 1. Furthermore, Oshlack *et al.* teach that the controlled release coatings are aqueous dispersions of hydrophobic acrylic polymers. See column 7, lines 35-38. Oshlack *et al.* also teach that the monomers to be used in the polymer coatings may include vinyl esters, such as vinyl acetate and vinyl chloride. See column 7, lines 50-53. Also, the pore former can be selected from a large group, including alkali metal salts, such as potassium chloride. See column 10, line 45 – column 11, line 42. The active agent can be selected from a large list of actives. See column 16, line 42 – column 17, line 44.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oshlack *et al.*, as discussed above, and in view of the following comments.

Oshlack *et al.* is described above as teachings applicant's claimed process. Oshlack *et al.* does not specifically teach the claimed particle size for the pore formers. However, it is the position of the examiner that the determination of a particular particle size is within the skill of the ordinary worker as part of the process of normal optimization, and therefore, does not render patentable weight to the claims.

Additionally, Oshlack *et al.* does not specifically teach each of applicant's listed pore formers. However, Oshlack *et al.* does teach the use of pore formers, in general, to create a controlled release composition. Furthermore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any pore former in the process taught by Oshlack *et al.*, because Oshlack *et al.* teaches the inclusion of pore formers, in general. The expected result would be a controlled release formulation, where the pore formers act to create channels and pores that fill with the environmental fluid. See column 10, lines 40-44. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

aep

June 27, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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